

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This document relates to:
All Actions

No. 1:19-md-2875-RBK

Hon. Robert B. Kugler
Hon. Thomas I. Vanaskie

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO
ZHP'S MOTION TO SEAL**

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INTRODUCTION

ZHP has over designated its document production as confidential. This is not conjecture, but rather a fact. Seeking to create and capitalize on fatigue over this issue, and its perception that this strategy is working, ZHP continues to file motions to seal in a manner that creates significant extra work and inconvenience for the Parties and the Court. For example, Plaintiffs must contend with over designated documents every time they brief the substantive issues of this case. This is not just a matter of easily identifying and addressing the designations with little effort—on every motion implicating the purportedly confidential information—which is virtually every motion, Plaintiffs are required to spend significant time attempting to discern ZHP’s designations of documents and transcripts and then meticulously sift through their filings to redact such information. ZHP knows this, but continues to obstinately maintain its overreaching designations, even in the face of the Court’s prior denials of motions to seal similar documents, likely now emboldened by its perception that the Court has no appetite to continue to address this issue.

ZHP has compounded the prejudice and burden of its over designations by missing deadlines to maintain those designations, dragging these issues out longer than the governing order contemplated, and then deflecting to blame Plaintiffs, despite the fact that the Protective Order explicitly calls for waiver when a deadline to move to seal is missed. The self-executing provision of the Order was intended to streamline this process, avoiding the need to involve the Court where the deadline passes. In its most recent decision relating to this issue, the Court, signaling a preference to decide these issues on the merits despite ZHP’s technical waiver under the Order, applied the deadlines for unfiled discovery to certain court records. Plaintiffs continue to be required to spend significant amounts of time to meet and confer and then brief challenges to meritless designations in the midst of the briefing of serious substantive issues in this case, including both sides’ objections to the Court’s decision on Plaintiffs’ motion to amend, both sides’

Daubert briefing on their general causation experts, and Plaintiffs' motion for class certification of their economic loss and medical monitoring claims.

The Court recently cautioned Plaintiffs regarding the confidentiality designations, and ZHP appears to be emboldened to double down on its strategy. However, Plaintiffs have always been circumspect about the challenges presented to the Court. The problem is the vast proportion of documents in the production that are designated as confidential and the consequent need for Plaintiffs to continually challenge large numbers of documents. Plaintiffs respectfully submit that ZHP's effort to shield facts that relate to massive manufacturing failures in the production of regulated drugs from the public record is not mundane or harmless, but rather a subversion of the legal system intended to deprive anyone who might be interested in learning the truth about how the worldwide supply of valsartan was dangerously compromised. The results of the motions to date are illustrative of the extent of the problem, and that the fault lies with ZHP. When ZHP has filed its motions to seal these documents, the Court has denied more than eighty percent of its requests (and that failure rate does not include the number of documents ZHP declined to move on—meaning that Plaintiffs had to go to the trouble of redacting and filing varying versions of their papers, only for ZHP to later casually admit the document should not have been designated in the first place). **Notwithstanding, Plaintiffs are cognizant of the Court's advice and have withdrawn what are believed to be legitimate challenges to two lab notebooks, at ZHP02710344 (ECF 1405, Ex. 15) and ZHP02710242 (ECF 1405, Ex. 16).**

For the Court's benefit, Plaintiffs offer an example to help demonstrate the extent and depth of the over-designation problem Plaintiffs are forced to contend with. **ZHP has inexplicably designated as confidential a recall notice/press release that was made public at the time of the recall.** Plaintiffs consequently had to redact their discussion of this recall notice/press release and add slip sheets for the exhibit on ECF in their *Daubert* motions to exclude the opinions of

defense experts Dr. Janice K. Britt and Dr. Daniel Catenacci. ([ECF 1704-2](#), p. 17; [ECF 1705-2](#), p. 15, Ex. T in both filings). This is only one example of the hundreds of times Plaintiffs have had to do so. On this motion, ZHP continues to maintain the confidentiality of documents containing public information. For example, the Court has previously explained that ZHP's alleged confidentiality agreement with Novartis does not warrant sealing information concerning their relationship and interactions (Novartis discovered the contamination and forced ZHP to disclose it to other customers and the authorities, triggering the recall). ([ECF 1269](#), p. 22-23 (declining to seal ZHP00310874, and explaining that **although “[t]he Xu Declaration asserts that disclosure of this information without authorization from its customer would violate a confidentiality agreement and cause ZHP financial harm,” “the information has already been disclosed in the context of this litigation”**)). Despite this, ZHP has ignored that ruling and asked the Court to seal ZHP02471924, ZHP02734673, ZHP02490581, and ZHP02735368. This just compounds the prejudice. The rest of ZHP's motion inexplicably discloses the substance of the documents at issue or drastically mischaracterizes the significance of that information.

Finally, Plaintiffs want to be clear that they are cognizant of the Court's recent caution regarding confidentiality designation challenges; however, as the Court is well aware, the public health implications of this information cannot be disputed. The public's right to access these documents as court records concerning the widespread contamination of its drug supply is not a throw in or insignificant fact—this goes to the heart of what this litigation is about. ([12/18/2019 Tr. 23:20-24:9](#) (the Court stating: “With regard to the burden issue, quite frankly, that's not a big factor in the Court's decision. This case is enormous. The potential damage claim in this case is enormous. **There is tremendous public interest in this case. It has enormous public health consequences -- whether a very popular drug supplied in the United States was contaminated or not. Given the public interest and the health and welfare implications, when it comes to**

evaluating the burden to the defendant in the case, the Court has to take that into consideration. It's not just a simple matter of dollars and cents, but on this particular issue, it really isn't a dollar and cents issue as far as the Court's concerned.” (emphasis added)).

This final point is especially relevant with regard to ZHP02710347, [REDACTED]

[REDACTED]. ZHP cannot continue to violate the law and hide the evidence of its egregious misconduct.

Plaintiffs submit that the best way for the Court to bring this process to a close is to clearly rule that the over-designations are inappropriate, not to pressure Plaintiffs to “let it go,” as ZHP apparently interprets the Court’s recent admonition. The Court should deny ZHP’s motion in its entirety.

And Plaintiffs again ask that the Court employ the same tool that Judge Schneider previously employed with Torrent’s over-designations (*In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Products Liability Litigation*, 512 F. Supp. 3d 546, 556 (D.N.J. 2021)): requiring ZHP to re-evaluate its production, affirmatively de-designate across the board, and thus vastly narrow the field of documents potentially requiring challenges.

LEGAL ARGUMENT

I.

THE COURT SHOULD DENY ZHP'S MOTION TO SEAL

“[I]n cases involving large-scale discovery, the court may construct a broad umbrella protective order upon a threshold showing by the movant of good cause.” *In re Avandia Mktg., Sales, and Prods. Liab. Litig.*, 924 F.3d 662, 671 n.5 (3d Cir. 2019) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 n.17 (3d Cir. 1994)). **“However, Courts must be vigilant to assure Confidentiality Orders are not overused and are only used for legitimate purposes.”** *Valsartan*, 512 F. Supp. 3d at 550. This Court has previously noted that **“the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery.”** *Id.* (emphasis added). Here, it is ZHP that continues to try to hide the details of its wrongdoing and that should be brought to an end.

ZHP carries the burden on this motion; when a party challenges a designation under an umbrella protective order, “the party seeking to maintain the seal must justify the continued sealing of those documents.” *Avandia*, 23 F. 3d at 671 n.5 (quoting *Pansy*, 23 F.3d at 787 n.17). “In *Pansy v. Stroudsburg*, 23 F. 3d 772 (3rd Cir. 1994), the court expounded on the burden to justify confidentiality.” *Valsartan*, 512 F. Supp. 3d at 550. There, the Third Circuit set forth seven factors to consider when deciding a motion to seal:

1. whether disclosure will violate any privacy interests;
2. whether the information is being sought for a legitimate purpose or for an improper purpose;
3. whether disclosure of the information will cause a party embarrassment;
4. **whether confidentiality is being sought over information important to public health and safety;**

5. whether the sharing of information among litigants will promote fairness and efficiency;

6. whether a party benefitting from the order of confidentiality is a public entity or official; and

7. **whether the case involves issues important to the public.**

Avandia, 924 F.3d at 671 (emphasis added) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995) (citing *Pansy*, 23 F.3d at 787-91)); *see also* [ECF 1269](#), p. 6-7. In *Pansy*, the Third Circuit also held that “**where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality** whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law.” 23 F.3d at 791; *see also* [ECF 1269](#), p. 7. Importantly, this standard, which ZHP cannot meet—just as Torrent could not meet it—applies “when [a court] review[s] orders preserving the confidentiality of discovery materials pursuant to Federal Rule of Civil Procedure 26.” *Avandia*, 924 F.3d at 670 (citing *Pansy*, 26 F.3d at 783-92); *see also* [ECF 1269](#), p. 7. All of these factors cut against ZHP, which has the heavy burden on this motion.

“**[T]he more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access.**” *Avandia*, 924 F.3d at 670 (emphasis added) (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)); *see also* [ECF 1269](#), p. 7.

The common law right of access “antedates the Constitution.” *Bank of Am. Nat’l Tr. & Sav. Ass’n v. Hotel Rittenhouse Assocs.*, 800 F.2d [339,] 343 [(3d Cir. 1986)]. The right of access “promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court.” *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access “diminishes possibilities for injustice, incompetence, perjury, and fraud.” *Id.*

Moreover, “the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness.” *Id.*

Avandia, 924 F.3d at 672. Thus, **once a document “has been filed with the court ... or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings,” “a presumption of access attaches.”** *Id.* (emphasis added) (quoting *In re Cendant Corp.*, 260 F.3d at 192); *see also* [ECF 1269](#), p. 8.

“To overcome that strong presumption, the District Court must articulate ‘the compelling, countervailing interests to be protected,’ make ‘specific findings on the record concerning the effects of disclosure,’ and ‘provide[] an opportunity for interested third parties to be heard.’” *Avandia*, 924 F.3d at 672-73 (quoting *In re Cendant Corp.*, 260 F.3d at 194); *see also* [ECF 1269](#), p. 8. “In delineating the injury to be prevented, specificity is essential,” so **“[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient.”** *Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (emphasis added); *see also* [ECF 1269](#), p. 8. In sum, **“[c]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants.”** *Avandia*, 924 F.3d at 673 (emphasis added) (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)); *see also* [ECF 1269](#), p. 8. ZHP’s motion is built entirely on broad allegations of harm, nothing more—there is insufficient information submitted on this motion for the Court to make the findings necessary to find in ZHP’s favor (and this cannot be fixed on the reply).

A court’s analysis is intended to be inhospitable to the types of concerns at the foundation of the over-designations here, regardless of how ZHP tries to dress up its position. *Avandia*, 924 F.3d at 677. First, the Third Circuit has “repeatedly said that **concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the**

presumption of public access.” *Id.* (emphasis added) (collecting cases). Second, “a person's motive for inspecting or copying judicial records is irrelevant under the common law right of access.” *Id.* at 677.

The Third Circuit has put its “thumb on the scale in favor of openness—the strong presumption of public access” in exactly this situation:

[T]he public's right of access must be the starting point, not just one of multiple factors. The scale is tipped at the outset in favor of access. And the right of access is not a mere formality—it “promotes public confidence in the judicial system”; “diminishes possibilities for injustice, incompetence, perjury, and fraud”; and “provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness.” *Littlejohn*, 851 F.2d at 678. **These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.**

Avandia, 924 F. 3d at 677 (emphasis added). **Moreover, “[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm.”** *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196) (emphasis added).

That showing cannot be made by ZHP since the extensive cGMP failures causing the contamination are a matter of public record, and the failed manufacturing processes at issue are banned. In other words, at this point we are looking back at a cautionary tale, one that every regulator and responsible scientist and physician has already agreed should never happen again. Moreover, “blanket assertions of harm that ‘could’ come to fruition fall short of the clearly defined and serious injury that [a movant] must articulate to obtain sealing under any standard.” *Id.* at 679. As discussed below, ZHP fails that test, and cannot meet it with regard to presumptively public documentation of the facts surrounding its wholesale contamination of a trusted blood pressure drug, a drug that is no longer sold by ZHP in the United States.

After the Third Circuit vacated and remanded its original decision to seal the documents in *Avandia*, the trial court applied the correct standard and wrote:

Justice Brandeis famously declared that “sunlight is the most powerful of all disinfectants.” Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents. Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.

In re Avandia Mktg, Sales Practices and Prods. Liab. Litig., 484 F. Supp. 3d 249, 268 (E.D. Pa. 2020) (emphasis added) (footnote and citations omitted).

Of great significance here, in one of its prior confidentiality rulings in this case, the Court noted that it “is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents.” *Valsartan*, 512 F. Supp. 3d at 553. The Court also rejected the argument that its decision was impacted because the authors or recipients expected the documents to remain confidential, explaining “[o]therwise, large swatches of routine emails would be kept under wraps.” *Id.* The Court explained, “General allegations of injury to reputation and client relationships or embarrassment that may result ... is insufficient to justify judicial endorsement of an umbrella confidentiality agreement.” *Id.* (quoting *Barnes Found. Twp. of Lower Merion*, C.A. No. 96-372, 1996 WL 729885, at *3 (E.D. Pa. Dec. 6, 1996)). This is in line with Judge Kugler’s decision in *In re Forest Research Institute, Inc.*, No. 13–1845 (RBK/AMD), 2014 WL 12618100 (D.N.J. June 16, 2014), Ex. A hereto. There, **Judge Kugler denied an *unopposed* motion to seal, explaining that “[m]erely because a document is designated ‘confidential’ does not necessarily mean that document satisfies the criteria for sealing.”** *Id.* at *2. He added that “even if the confidential nature of these documents did somehow satisfy the criteria for sealing, [movants] fail to explain the clearly defined and serious injury that would result if the relief sought is not granted.” *Id.* *Centennial Mill by Del Webb Community*

Association, Inc. v. Ply Gem Holdings, Inc. is also instructive on this issue, demonstrating that self-serving arguments are unavailing:

In opposition to Plaintiff's Motion to Reman[d], to demonstrate the inapplicability of the forum selection clause, Defendants relied, in part, on the Confidential Documents, which include confidential settlement communications pertaining to the resolution of the Prior Lawsuit and the negotiation of the Settlement Agreement. Additional documents and discussion pertaining to settlement and negotiations were relied upon by Plaintiff in Reply.

Defendants argue disclosure of this information would "cause substantial harm to Defendants and impair their ability to defend against other claims of alleged 'Thermal Distortion.'" Defendants argue they have been sued, and may later be sued, in other matters relating to thermal distortion, and that "public access to the Confidential Documents will provide other/future claimants or co-defendants the opportunity to attempt to utilize the information therein in pursuit of liability claims against Defendants, and thus, such disclosure will impair Defendants' ability to effectively defend against other/future disputed claims."

No. 1:17-cv-7675 (NLH/JS), 2018 WL 3085210, at *5 (D.N.J. June 22, 2018), Ex. B hereto. This description of harm far exceeds what ZHP has provided here. Yet, the Court found that the defendants "failed to justify their Motion to Seal with regard to convincing this Court that there are 'legitimate private or public interest[s] which warrant the relief sought' and that 'clearly defined and serious injury ... would result if the relief sought is not granted.'" *Id.* (quoting Local Rule 5.3). The court explained:

The Court has closely reviewed the documents Defendants ask the Court to seal and cannot discern a legitimate private or public interest warranting sealing, nor a serious injury that would result to Defendants. **Defendants' index is not persuasive, as it does not state with particularity any harm that would result.** Rather, Defendants' index broadly claims: "Public access to information concerning the alleged 'thermal distortion' in settlement communications and negotiation could disadvantage Defendants in other matters/litigations." Preliminarily, **some of the information Defendants ask the Court to seal can be obtained, or easily inferred, from documents already publicly filed**, such as the

length of the settlement negotiations, that the state court litigation concerned the thermal distortion phenomenon, and the definition of thermal distortion.

However, even as to other information that might not be available to the public now, the Court does not find sufficient basis to seal. **This Court has repeatedly emphasized the public interest in the disclosure of materials filed on this Court's docket, which often outweighs private interests in confidentiality. This Court is funded by the public and does not sit, in general, to resolve private disputes in secret.** Finding Defendants lack a legitimate justification to warrant sealing the identified information, the Court will deny Defendants' Motion to Seal in full.

Id. at *5-6. Importantly, this MDL is not even a private dispute. It concerns hundreds of personal injury cases and class actions involving millions of class members, all related to the worldwide recall of Defendants' contaminated drugs.

Thus, as this Court has previously held, an entity's mere designation of a document as confidential is irrelevant to whether it actually is confidential once it is filed with the Court. *Valsartan*, 512 F. Supp. 3d at 554; *Forest Research*, 2014 WL 12618100, at *2; *Centennial Mill*, 2018 WL 3085210, at *5-6. After all, it is the movant's burden to overcome the public's right to access and prove a document warrants sealing based on "the kind of information" contained in the document and a specific showing "that disclosure will work a clearly defined and serious injury to the party seeking closure." *Avandia*, 924 F.3d at 672; *see also* [ECF 1269](#), p. 8.

ZHP Cannot Meet Its Burden

In this motion, ZHP has asked the Court to seal eight exhibits from [ECF 1405](#), which is Plaintiffs' Motion to Compel ZHP's Supplemental Production. ZHP has previously moved to seal parts of briefs describing "confidential" exhibits, but it has not done so here. (*Compare* [ECF 1468-3](#), p. 13, *with* [ECF 1629-3](#), p. 29). Thus, ZHP's position must be that AT MOST, the documents should be redacted, and NOT with regard to the information on which the descriptions of the documents in [ECF 1405](#) are based. However, ZHP's motion seeks full sealing, and since the

burden to prove the need to fully the documents cannot be met under any circumstances, the motion should be denied as to those documents.

ZHP's proposed order also concedes that the common law public right of access applies to the rest of the material at issue. ([ECF 1629-3](#), p. 14). *See also Avandia*, 924 F.3d at 672. In addition to "the strong presumption" against sealing these judicial records, and the fact that there is nothing sensitive about the documents on their face—certainly not at present, years after the events occurred, this Court should recognize the significant public interest in understanding the nitrosamine contamination at issue in this case. *Avandia*, 924 F. 3d 677-78. ZHP was the first pharmaceutical manufacturer to recall its drugs due to their contamination with carcinogenic nitrosamines, and the issue is not limited to valsartan, losartan, and irbesartan. FDA, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, <https://tinyurl.com/1k9w9jid>; FDA, *Information about Nitrosamine Impurities in Medications*, <https://tinyurl.com/1tu3nih0>. **There is an ongoing public investigation into the cause of this widespread contamination, whether it has occurred with other drugs, and how to prevent it in the future, on top of the FDA's firm determination that the contamination was wrongful and unacceptable, resulting in a complete recall and import ban against ZHP.** In fact, ZHP is still banned from importing its valsartan into the United States because it has not addressed its contamination to the satisfaction of the FDA. FDA, Import Alert 66-40, <https://tinyurl.com/3jxjmcxc>. And this is all an overlay to the fact that the documents at issue do not merit confidentiality on their face.¹ As explained in further detail below, this Court should deny ZHP's motion to seal.

¹ **ZHP cites six trial court decisions, all but one of which are unpublished and unopposed, in support of its motion.** ([ECF 1629-3](#), p. 20-22). *Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at *1 (D.N.J. Dec. 6, 2018), *Valeant Pharm.*

1. ZHP02471924 & ZHP02734673 (ECF 1405, Ex. 4 & 5): Plaintiff first note that these two documents are duplicates. More substantively, in its declaration in support of sealing this document, ZHP divulges the substantive information found therein, thus it cannot be confidential by definition. ([ECF 1629-5](#), p. 1-2; [ECF 1661](#), § 9). Moreover, it is public knowledge that Novartis discovered the NDMA contamination and had been buying valsartan from ZHP since 2012. Edney, Berfield, & Yu, *Carcinogens Have Infiltrated the Generic Drug Supply in the U.S.: An FDA quality-control nightmare reveals how impurities end up in America's blood pressure pills*, BLOOMBERG BUSINESSWEEK (Sept. 12, 2019), <https://tinyurl.com/y659ryj9>. Thus, the information in this document is a routine business communication concerning facts that are already public. ([ECF 1269](#), p. 22-23 (declining to seal ZHP00310874, and explaining that **although “[t]he Xu Declaration asserts that disclosure of this information without authorization from its customer would violate a confidentiality agreement and cause ZHP financial harm,” “the information has already been disclosed in the context of this litigation”**)). ZHP’s willingness to include the substance of the document in its public declaration completely undermines its

Luxembourg S.à r.l. v. Actavis Labs. UT, Inc., No. 2:16- cv-4344, 2018 WL 1469050, at *3 (D.N.J. Mar. 26, 2016), *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 1:14-cv-4727, 2015 WL 4715307, at *1 (D.N.J. Aug. 7, 2015), *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 WL 27460 (D.N.J. Jan. 3, 2017), and *Novartis Pharmaceuticals Corp. v. Mylan Pharmaceuticals, Inc.*, No. 06-2885 (MLC), 2008 WL 11383884, at *1 (D.N.J. Oct. 31, 2008), were all unopposed motions to seal. Mylan even wrote in support of Boehringer’s motion to seal in *Boehringer*, 2015 WL 4715307, at *1. These cases do not support granting ZHP’s motion here. In the fifth case—*In re Gabapentin*, 312 F. Supp.2d 653, 669 (D.N.J. 2004)—the court denied an investment research company’s motion to unseal summary judgment papers filed in pharmaceutical patent holder’s infringement suit against prospective manufacturers of generic version. In that case, the investment research company’s entire purpose was to uncover information for the competitive benefit of others. Here, ZHP’s motion attempts to prevent the public from understanding how its drug supply became contaminated with carcinogenic nitrosamines and when ZHP knew about that contamination. To the extent they contain any scientific information, the documents concern manufacturing practices that neither ZHP nor its competitors could use now that their manufacturing defects are widely known and acknowledged by ZHP itself. *Gabapentin* is consequently of no import to this case.

position that any confidentiality agreement applies to this document. As already explained, even if such an agreement exists, it is irrelevant to this Court's analysis anyway. *See Valsartan*, 512 F. Supp. 3d at 554; *Forest Research*, 2014 WL 12618100, at *2; *Centennial Mill*, 2018 WL 3085210, at *5-6. Almost lost in the shuffle is the fact that ZHP has not included a copy of the allegedly applicable confidentiality agreement in support of this motion, and it has not proffered that it requested Novartis' approval to allow this document to become public or Novartis' response and justification for refusing to provide any such approval.

Although the enclosed spreadsheet contains some information that is not public, neither ZHP nor Novartis has explained how allowing the public to access that limited information would "work a clearly defined and serious injury to" either of them, as required. *Avandia*, 924 F.3d at 672. And they could not because the spreadsheet's limited information concerning Novartis' purchase and return of ZHP's contaminated valsartan is of no use to any competitors at this time. *Avandia*, 924 F. 3d at 678 (stating that "[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm" (quoting *In re Cendant Corp.*, 260 F.3d at 196)). ZHP has not met its burden of establishing the compelling need for confidentiality of this document.

2. ZHP02490581 & ZHP02735368 (ECF 1405, Ex. 6 & 7): As with the two prior documents, these two documents are duplicates as well as routine business communications between ZHP (the seller of valsartan contaminated with a carcinogen) and Novartis (the company that bought this drug and discovered the contaminant). The first enclosure concerns various claims made against Novartis related to these public facts that have been filed in public courts around the world. ZHP has not even claimed, much less proven, that any of these claims are not public, presumably because they are public. *See, i.e., Charney Lawyers, Valsartan Class Action*, <https://tinyurl.com/uk4fmuw> (stating: "The Québec action in regards to Valsartan has been

temporarily stayed pursuant to the order of the Superior Court of Québec. You can find the order [here](#). The action will be proceeding in the Superior Court of Ontario.”). The second enclosure also concerns many publicly filed lawsuits, and to the extent it does not, it is routine for a company to indemnify the purchaser of an admittedly defective product against claims related to that product (there is nothing secret about that). ([ECF 1269](#), p. 22-23 (declining to seal ZHP00310874 involving Novartis despite the existence of an allegedly applicable confidentiality order, because it contained public information)). If anything, the public disclosure of this information should benefit, not harm Novartis.

For sake of completeness, Plaintiffs incorporate their argument concerning the Court’s previous finding as to the lack of relevance of any confidentiality agreement here.

3. ZHP02731217 (ECF 1405, Ex. 8): Once again, ZHP’s declaration contains most of the substance of this two-line email, undercutting the bald contention that ZHP has agreed to keep this document confidential. ([ECF 1629-6](#), p. 1-2). The remaining information is so limited that it cannot possibly be of any benefit to ZHP’s competitors. As always, ZHP acts as though this case does not also concern its irbesartan, which it recalled due to its contamination for the same reasons as with valsartan, with the carcinogen NDEA. *See* FDA’s Recall Announcement Regarding ZHP’s Irbesartan, <https://tinyurl.com/3eanb2sf>. ZHP’s attempt to invoke its current ban from importing drugs into the United States as somehow supporting the sealing of materials in this litigation is not even logical. That fact militates for de-designation. The public has a right to this information to continue to protect itself from ZHP’s gross violations of cGMPs. *See Avandia*, 924 F. 3d at 677; *Avandia*, 2020 WL 5358287, at *12. The Court should consequently deny ZHP’s motion to seal this document.

4. ZHP00180427 (ECF 1405, Ex. 9): ZHP admits that this email concerns its inaccurate chromatography testing of its valsartan in 2017. This email does not state that the testing found

the nitrosamines that were present in ZHP's valsartan at that time. The email contains no proprietary information, as everyone knows that the testing was completely inadequate, and so no competitor would seek to replicate it for its own advantage. Moreover, the public has a significant interest in understanding the cautionary tale of the inadequacy of chromatography that allegedly failed to detect the nitrosamine contamination of its valsartan. *See Avandia*, 924 F. 3d at 677; *Avandia*, 2020 WL 5358287, at *12. (See also [ECF 1269](#), p. 11-13, 22-23 (declining to seal ZHP00479762, ZHP00493010, ZHP00423144, ZHP00310874, and ZHP02125655, all very similar documents concerning ZHP's inadequate chromatography testing)). Therefore, the Court should deny ZHP's motion to seal this document.

For the sake of completeness, Plaintiffs incorporate their argument concerning any confidentiality agreement that might have existed.

5. ZHP02628144 (ECF 1405, Ex. 10): ZHP once again discloses the substance of this email chain in its declaration supporting the sealing of this document. ([ECF 1629-5](#), p. 4). This is not surprising because it is a routine business communication, but it also undercuts the claimed confidentiality of the document and the possibility that there is any confidentiality agreement rendering it somehow confidential. The public clearly has a right to access this routine business communication now that it is a court record. *See Avandia*, 924 F. 3d at 677; *Valsartan*, 512 F. Supp. 3d at 554; *Avandia*, 2020 WL 5358287, at *12. (See also [ECF 1269](#), p. 21 (declining to seal ZHP00476678, another routine business communication). The Court should deny ZHP's motion to seal this document.

For the sake of completeness, Plaintiffs incorporate their argument concerning any confidentiality agreement that might have existed.

6. ZHP02710347 (ECF 1405, Ex. 14): This document is a research and development report related to the July 27, 2017 email, the contents of which the Court is familiar with based on

the briefing on the confidentiality of the September 10, 2021 transcript and the discussion of that email therein. (*See* Pls.’ Opp. to ZHP’s Mot. to Seal the September 10, 2021 transcript). As already explained, ZHP ultimately recalled its irbesartan because it was contaminated with NDEA. FDA’s Recall Announcement Regarding ZHP’s Irbesartan, <https://tinyurl.com/3eanb2sf>. As the Court knows from Plaintiffs’ motion to compel ZHP’s supplemental production, ZHP has not produced the native version of this document, which was clearly created using a computer, and the metadata does not include real dates (only “12/31/9999 11:59 PM EST”). However, **Plaintiffs know that this report predates the recall of ZHP’s irbesartan and valsartan because** [REDACTED]

[REDACTED] (4/22/2021 Min Li Dep. Tr. 139:2-7 (emphasis added), Ex. C hereto). Min Li’s declaration omits this crucial detail regarding [REDACTED], which shows that both ZHP and Min Li are more concerned about hiding [REDACTED] than protecting any proprietary information from their competitors, who have no interest in copying the defective manufacturing processes discussed in this report. Although the report contains technical information, it is mundane technical information regarding the findings on testing of a drug that everyone now knows was contaminated. None of this is of any use to competitors [REDACTED]

[REDACTED]:

- [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] (ZHP02710348 (emphasis added), Ex. D hereto).²

- [REDACTED]
[REDACTED]
[REDACTED]
(ZHP02710350, Ex. D hereto).

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (ZHP02710351, Ex. D hereto).

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (ZHP02710351 (emphasis added), Ex. D hereto).

ZHP wants to hide the fact that [REDACTED]
[REDACTED]

² Although ZHP bears the burden on this motion, Plaintiffs have provided the English translation of this document.

[REDACTED]

[REDACTED]. This is the antithesis of the type of information that this Court can properly seal on its docket. *See Avandia*, 924 F. 3d at 677 (holding that “we have repeatedly said that concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access”); *Valsartan*, 512 F. Supp. 3d at 550 (holding that “the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery”). **The public’s right to access the information necessary to understand and prevent this type of widespread contamination of its drug supply greatly outweighs ZHP’s illegitimate interest in hiding its own willful wrongdoing.** *See Avandia*, 924 F. 3d at 677; *Avandia*, 2020 WL 5358287, at *12. (See also [ECF 1269](#), p. 10-11, 13-14 (declining to seal ZHP00385769 and PRINBURY00129588, a deviation investigation report into the nitrosamine contamination of valsartan and a draft response to the FDA’s observation that ZHP inadequately tested its valsartan for genotoxic impurities, respectively). ZHP has provided no specific information clearly defining how public access to this information would be damaging to anything other than its reputation—for example, how a competitor might use this information to change its testing processes to obtain a defined commercial advantage, since no competitor would have any interest in repeating ZHP’s conduct, and the industry is now abundantly familiar with the need for this type of testing and the proper manner to conduct it.

CONCLUSION

For the foregoing reasons, the Court should deny ZHP's motion to seal. In accordance with Local Civil Rule 5.3, Plaintiffs have attached a proposed order as Exhibit E of this brief.

Dated: November 8, 2021

Respectfully Submitted,

/s/ Ruben Honik

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CERTIFICATE OF SERVICE

I hereby certify that on November 8, 2021, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Adam M. Slater

Adam M. Slater